CLAIMS

128. Cancelled.

129. Cancelled

130. Cancelled

131. Cancelled

132. (New) A method for administering a stable FSH formulation to a patient comprising:

providing a vial containing a pharmaceutical formulation including human FSH consisting of an α-subunit having SEQ ID NO:5 and a β-subunit having SEQ ID NO:6, held together by noncovalent interactions,

said human FSH being present as the biologically-active, heterodimeric protein form of human FSH at a concentration of 5.0 μg/mL to 2 mg/mL,

said formulation further including benzyl alcohol in an amount effective to act as a preservative for the formulation;

first administering to the patient from said vial a first quantity of formulation, the first quantity including a pharmaceutically-effective amount of FSH; and

second administering to the patient from said vial a second quantity of formulation, the second quantity including a pharmaceutically-effective amount of FSH; the second quantity being administered to said patient greater than 24 hours after said first administering.

133. (New) The method of claim 132 in which said human FSH is present as the biologically-active, heterodimeric protein form of human FSH at a concentration of 50μg/mL to 200 μg/mL.

134. (New) The method of claim 132 in which the FSH is recombinant FSH.

135. (New) The method of claim 132 and which further includes administering to the patient from said vial one or more additional quantities of formulation, each additional quantity including a pharmaceutically-effective amount of FSH.

136. (New) The method of claim 135 in which said administering occurs over a period of several days.

137. (New) The method of claim 136 in which said administering continues for a cycle of treatment of the patient.

138. (New) The method of claim 132 in which each of said first administering and said second administering comprises injecting the formulation into the patient.

139. (New) A method for administering follicle stimulating hormone (FSH), the method comprising:

providing a pharmaceutical composition comprising an aqueous diluent, human FSH, and benzyl alcohol, said human FSH consisting of an alpha-subunit having SEQ ID NO:5 and a beta-subunit having SEQ ID NO:6, the alpha-subunit and beta-subunit held together by noncovalent interactions, said human FSH being present as the biologically-active, heterodimeric protein form of human FSH at a concentration of about 5.0 μg/ml to 2 mg/ml, said benzyl alcohol being present in said aqueous diluent in an effective anti-microbial amount;

injecting a first portion of the pharmaceutical composition into a human in need of ovarian follicle or testicular stimulation, said injecting a first portion providing an effective dose of biologically active human FSH for ovarian follicle or testicular stimulation in the human;

injecting a second portion of the pharmaceutical composition into the human at least 24 hours after said injecting a first portion, said injecting a second portion providing an effective dose of biologically active human FSH for ovarian follicle or testicular stimulation in the human.

140. (New) The method of claim 139, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

141. (New) The method of claim 140, wherein the pharmaceutical composition exhibits a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37° C for 24 hours.

142. (New) The method of claim 139, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

143. (New) A method for treating a patient, comprising:

providing a pharmaceutical composition comprising an aqueous diluent, benzyl alcohol, and human FSH, said human FSH being present in said pharmaceutical composition in a solubilized biologically-active, heterodimeric protein form consisting of an alpha-subunit having SEQ ID NO:5 and a beta-subunit having SEQ ID NO:6, the alpha-subunit and beta-subunit held together by noncovalent interactions, said human FSH being present in the biologically-active, heterodimeric protein form at a concentration of about 5.0 μg/ml to 2 mg/ml, said benzyl alcohol being present in said pharmaceutical composition in an effective anti-microbial amount;

holding the pharmaceutical composition for at least 24 hours; and

after said holding, administering an amount of said pharmaceutical composition to a human so as to provide an effective dose of human FSH for ovarian follicle or testicular stimulation in the human.

144. (New) The method of claim 143, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

145. (New) The method of claim 144 in which said pharmaceutical composition exhibits a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37° C for 24 hours.

146. (New) The method of claim 143, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

147. (New) A method for treating a patient, comprising:

providing a pharmaceutical composition comprising an aqueous diluent, human FSH, and benzyl alcohol, said human FSH being present in said pharmaceutical composition in a solubilized biologically-active, heterodimeric protein form consisting of an alpha-subunit having SEQ ID NO:5 and a beta-subunit having SEQ ID NO:6, the alpha-subunit and beta-subunit held together by noncovalent interactions, said human FSH being present in the biologically-active, heterodimeric protein form at a

concentration of about 5.0 μg/ml to 2 mg/ml, said benzyl alcohol being present in said pharmaceutical composition in an effective anti-microbial amount;

first administering a first portion of the pharmaceutical composition to a patient in need of ovarian follicle or testicular stimulation, said administering providing an effective dose of biologically active human FSH for ovarian follicle or testicular stimulation in the patient;

second administering a second portion of the pharmaceutical composition to the patient at least 24 hours after said first administering, said second administering providing an effective dose of biologically active human FSH for ovarian follicle or testicular stimulation in the patient.

148. (New) The method of claim 147 wherein said pharmaceutical composition is adapted for administration by injection, and wherein said first administering and said second administering both comprise injecting the pharmaceutical composition into the human.

149. (New) The method of claim 147 wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

150. (New) The method of claim 149 wherein the pharmaceutical composition exhibits a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37° C for 24 hours.

151. (New) The method of claim 147, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

152. (New) A method for providing a stable, multi-use FSH formulation comprising:

preparing an aqueous pharmaceutical formulation comprising human FSH and benzyl alcohol, said human FSH consisting of an α-subunit having SEQ ID NO:5 and a β-subunit having SEQ ID NO:6 held together by noncovalent interactions, said human FSH being present as the biologically-active, heterodimeric protein form of human FSH

at a concentration of 5.0 μg/mL to 2 mg/mL, said benzyl alcohol being present in an amount effective to act as a preservative for the formulation; and

placing the formulation into a vial.

153. (New) The method of claim 152 and which further includes storing the vial at 2-40 degrees C for a period of time exceeding 2 months.

154. (New) The method of claim 152 which comprises placing in said vial an amount of pharmaceutical formulation sufficient for administering to a patient multiple doses of a pharmaceutically-effective amount of human FSH.

155. (New) The method of claim 154 in which the amount is sufficient for administering a pharmaceutically-effective amount of human FSH for several days.

156. (New) The method of claim 155 in which the amount is sufficient for administering a cycle of treatment to the patient.

157. (New) The method of claim 152 which comprises placing the formulation into a pen-injector system.

158. (New) A method for preparing a stable, reconstituted formulation comprising:

providing a lyophilized mixture of FSH and a lyoprotectant;

providing an aqueous diluent containing benzyl alcohol;

reconstituting the mixture with the diluent such that the resulting formulation contains human FSH consisting of an α-subunit having SEQ ID NO:5 and a β-subunit having SEQ ID NO:6 held together by noncovalent interactions, said human FSH in the reconstituted mixture being present as the biologically-active, heterodimeric protein form of human FSH at a concentration of 5.0 μg/mL to 2 mg/mL, and an effective antimicrobial amount of benzyl alcohol.

159. (New) A pharmaceutical composition, comprising:

an aqueous diluent;

benzyl alcohol; and

human FSH;

said human FSH being present in said pharmaceutical composition in a solubilized biologically-active heterodimeric protein form consisting of an alpha-subunit

having SEQ ID NO:5 and a beta-subunit having SEQ ID NO:6, the alpha-subunit and beta-subunit held together by noncovalent interactions;

said human FSH being present in the biologically-active, heterodimeric protein form at a concentration of about 5.0 μg/ml to 2 mg/ml;

said benzyl alcohol present in said pharmaceutical composition in an effective anti-microbial amount.

160. (New) The pharmaceutical composition of claim 159, wherein said human FSH present in said pharmaceutical composition is in sufficient amount to administer multiple instances of an effective dose of the human FSH for ovarian follicle or testicular stimulation in a human.

161. (New) The pharmaceutical composition of claim 160, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

162. (New) The pharmaceutical composition of claim 161, exhibiting a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37° C for 24 hours.

163. (New) The pharmaceutical composition of claim 160, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

164. (New) The pharmaceutical composition of claim 159, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

165. (New) The pharmaceutical composition of claim 164, exhibiting a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37° C for 24 hours.

166. (New) The pharmaceutical composition of claim 159, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

167. (New) A pharmaceutical product suitable for use in administering human FSH to a patient over a period of greater than 24 hours, comprising:

a vial containing the pharmaceutical composition of claim 159, wherein said human FSH is present in said vial in sufficient amount to administer multiple instances of an effective dose of the human FSH for ovarian follicle or testicular stimulation in a human.

168. (New) A pharmaceutical composition for administration of FSH to a patient, the pharmaceutical composition comprising:

an aqueous diluent comprising human FSH and benzyl alcohol;

said human FSH consisting of an alpha-subunit having SEQ ID NO:5 and a beta-subunit having SEQ ID NO:6, the alpha-subunit and beta-subunit held together by noncovalent interactions, said human FSH being present as the biologically-active, heterodimeric protein form of human FSH at a concentration of about 5.0 μg/ml to 2 mg/ml;

said benzyl alcohol being present in said aqueous diluent in an effective anti-microbial amount;

said pharmaceutical composition exhibiting a level of stability wherein said effective dose of biologically active FSH is provided when an amount of the pharmaceutical composition is administered to the patient after the pharmaceutical composition has been held for 24 hours.

169. (New) The pharmaceutical composition of claim 168 in which said human FSH is recombinant human FSH.

170. (New) The pharmaceutical composition of claim 168 in which said human FSH is substantially pure.

171. (New) The pharmaceutical composition of claim 168, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers.

172. (New) The pharmaceutical composition of claim 168, wherein greater than 99% of the FSH protein particles in the pharmaceutical composition are provided by said biologically active heterodimeric protein form.

173. (New) The pharmaceutical composition of claim 172, exhibiting a level of stability wherein greater than 99% of the FSH protein particles in the pharmaceutical composition have an average diameter of about 5.7 nanometers even after incubation of the pharmaceutical composition at 37°C for 24 hours.

174. (New) A pharmaceutical product suitable for use in administering human FSH to a patient over a period of greater than 24 hours, comprising:

a vial containing the pharmaceutical composition of claim 168, wherein said human FSH is present in said vial in sufficient amount to administer multiple instances of an effective dose of the human FSH for ovarian follicle or testicular stimulation in a human.